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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,383	03/29/2007	Michael Glen Orchard	AC-50-US	9092
50446 7590 12/07/2010 HOXIE & ASSOCIATES LLC 75 MAIN STREET, SUITE 301 MILLBURN, NJ 07041			EXAMINER MABRY, JOHN	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 12/07/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,383	Applicant(s) ORCHARD ET AL.	
	Examiner JOHN MABRY	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 20-35 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 21-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/10; 7/20/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1 and 3 are pending and rejected.

Claim 20 is allowable.

Claims 2 and 5-19 have been cancelled.

Claims 4 and 21-35 directed towards non-elected subject matter.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1, 3 and 20 are rejected under 35 U.S.C. 112, first paragraph, over enablement for “prodrugs” have been overcome in view of Applicant’s amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1625

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Rejection of claims 1, 3 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/055498 (PTO-1449) has been overcome in view of Applicant's arguments.

Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 1625

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

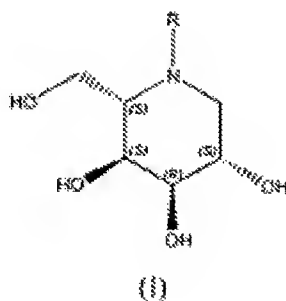
Rejection of claims 1 and 3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 13 of copending Application No. 10/522,207 is maintained.

Applicant argues the following:

The '207 application, although claims (2S,3S,4R,5S) 2-hydroxymethyl-3,4,5-trihydroxypiperidine compounds having a substituted benzyl substituent at the 1-position of the piperidine, the benzyl substituent is allowed to be substituted with very many different substituents, but a pentyloxy group.

Examiner respectfully disagrees with Applicant's allegation. US '207 claims compounds of Formula I where variable R is -C1alkyl Ar1 wherein Ar1 is phenyl which can be substituted by OR3 where R3 is C1-C6 alkyl - see claim one below:

1. (Previously presented) A compound of formula (I) in free or pharmaceutically acceptable salt form:



wherein

R is $-C_{1-3}$ alkylAr¹ where Ar¹ is phenyl;

wherein phenyl is substituted by one or more substituents selected from CN, CON(R³)₂, SO₂R², SO₂N(R¹)₂, N(R⁵)₂, N(R¹)COR², N(R¹)SO₂R², C₃₋₆ alkylAr², C₂₋₆ alkenylAr² and C₁₋₆ alkynylAr²

wherein one or more of the $-\text{CH}_2-$ groups of the alkyl chain may be replaced with a heteroatom selected from O, S and NR¹, provided that when the heteroatom is O, at least two $-\text{CH}_2-$ groups separate it from any additional O atom in the alkyl chain; or two adjacent substituents on the Ar¹ phenyl may together form a fused 5- or 6-membered saturated or unsaturated ring wherein the ring optionally contains 1 or 2 heteroatoms selected from O, S and NR⁴ and is optionally substituted by one or more substituents selected from, an oxo group, C₁₋₆ alkyl and C₀₋₃ alkylAr⁴;

and the Ar¹ phenyl is optionally substituted by one or more additional substituents selected from F, Cl, Br, CF₃, OCF₃, OR³ and C₁₋₆ alkyl;

R³ is H, or C₁₋₆ alkyl;

Applicant clearly the species of the instant application is encompassed by the genus as claimed in US '207; therefore the obviousness double patenting rejection is maintained.

Applicant also argues that the obviousness double patenting rejection is overcome in view of arguments set forth in 103 arguments over WO 02/055498. Examiner respectfully disagrees with Application's allegation. Examiner reminds

Art Unit: 1625

Applicant that double patenting rejections are based on a comparison of the claims in a patent and an application or between two applications. Applicant clearly the species of the instant application is encompassed by the genus as claimed in US '207; therefore the obviousness double patenting rejection is maintained - see arguments in previous paragraph.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1625

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/
Examiner
Art Unit 1625

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625